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DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106-2973

98-PHI-04

GEN. SPEC.
RELEASE
F# _____ DATE 11/24/97
Reviewed by: Lynn Bonner, CO

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

November 24, 1997

Mr. L. Douglas Lioon, President
Douglas Laboratories Div. of HVL, Inc.
600 Boyce Street
Pittsburgh, PA 15205

Dear Mr. Lioon:

On August 26, 1997, Food and Drug Administration (FDA) Investigator, Deborah A. Greenawalt conducted an inspection at Douglas Laboratories, Division of HVL, Inc., 600 Boyce Street, Pittsburgh, Pa 15205. Additionally, on 9/25/97, Investigator James O'Donnell collected samples of two products marketed by your firm at the same location: "Nutri-E" 180 Softgels and "Natural Vitamin E Complex 400 I.U." 100 Softgels.

This letter is in response to your firm's marketing and distribution of "Nutri-E 400", 100 Softgels and "Natural Vitamin E Complex 400 I.U.", 100 Softgels.

The immediate container Labeling of each product states in part, "*inhibits high levels of LDL (low density lipoprotein) cholesterol *". Statements regarding the treatment, prevention or reduction of high cholesterol levels are drug claims because such claims express an intent to treat cardiovascular disease.

Nutri-E and Natural Vitamin E Complex are drugs [Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act]. These products are also "new drugs" [Section 201 (p) of the Act] and, therefore, may not be marketed in the United Sates without an approved new drug application [Section 505 of the Act].

These drugs are also [Section 502 (f) (1) of the Act] because the labeling fails to bear adequate directions for use. In addition, the labeling is false and misleading because it suggests that the products are safe and effective for the intended uses when, in fact, this has not been established [Section 502(a) of the Act].

This letter is not intended to be an all inclusive review of all of the claims made in your labeling and promotional literature for your products. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Please notify this office in writing with fifteen (15) working days after the receipt of this letter as to the specific steps you have taken to correct the stated violations.

Please send your reply to the attention of Lynn S. Bonner, Compliance Officer, at the address noted above.

Sincerely,

Diana J. Kolaitis
District Director
Philadelphia District

cc: Pennsylvania State Department of Health
132 Kline Plaza, Suite A
Harrisburg, PA 17104
Attention: Robert E. Bastian, Director
Division of Primary Care and
Home Health Services